

AWARD NUMBER: W81XWH-14-2-0138

TITLE: The PTSD Practitioner Registry: An Innovative Tracking, Dissemination, and Support Tool for Providers in Military and Nonmilitary Settings

PRINCIPAL INVESTIGATOR: Josef I. Ruzek, Ph.D.

CONTRACTING ORGANIZATION: Palo Alto Veterans for Research and Education
Palo Alto, CA 94304

REPORT DATE: October 2016

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE October 2016		2. REPORT TYPE Annual		3. DATES COVERED 30 Sep 2015 - 29 Sep 2016	
4. TITLE AND SUBTITLE The PTSD Practitioner Registry: An Innovative Tracking, Dissemination, and Support Tool for Providers in Military and Nonmilitary Settings				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-14-2-0138	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Josef I. Ruzek				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Palo Alto Veterans for Research and EducationPalo Alto, CA 94304				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The PTSD Practitioner Exchange is an innovative research project for clinicians in three service sectors—the VA, DoD, and the community—which aims to disseminate the most recent clinically relevant information and resources supporting delivery of key practices endorsed in the VA-DoD Clinical Practice Guideline for the Management of PTSD; to support clinician well-being; and to identify factors enabling the implementation of clinical best practices in the treatment of PTSD. In order to provide this Exchange a two-phase study will be conducted. In Phase I, qualitative interviews are being conducted with 60 providers to assess practitioner needs and interests in the registry as well as pre-test the proposed registry survey. In Phase II, an RCT will be conducted to evaluate the impact of registry participation on practices/CPG awareness, receptivity and implementation. To date, the study team has completed the first phase of qualitative interviews and has enrolled 83% of the overall recruitment goal of 600 participants.					
15. SUBJECT TERMS PTSD, qualitative interviews, survey development, best practices, CPGs					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Unclassified	18. NUMBER OF PAGES 17	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER (include area code)

TABLE OF CONTENTS

	<u>Page No.</u>
1. Introduction	4
2. Keywords	4
3. Accomplishments	5
4. Impact	9
5. Changes/Problems	10
6. Products	12
7. Participants & Other Collaborating Organizations	14
8. Special Reporting Requirements	17
9. Appendices	17

1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

The delivery of best practice care for PTSD and other combat-related disorders is a compelling priority for clinicians working with active-duty Warriors and Veterans with Post Traumatic Stress Disorder (PTSD). The PTSD Practitioner Exchange is an innovative research project for clinicians in three service sectors—the VA, DoD, and the community—which aims to disseminate the most recent clinically relevant information and resources supporting delivery of key practices endorsed in the VA-DoD Clinical Practice Guideline for the Management of PTSD; to support clinician well-being; and to identify factors enabling the implementation of clinical best practices in the treatment of PTSD. This clinician-informed online survey and portal will connect providers with a wide array of resources and serve as a support mechanism for clinicians with the goal of increasing their knowledge of and receptivity to best practices, and ultimately improving the quality of care for Warriors and Veterans with PTSD as well as their families. It will also provide a way of monitoring the levels of burnout among PTSD treatment providers, assessing perceptions of the local organizational climates for implementing practices, and tracking awareness and implementation of key practices within the Clinical Practice Guideline. Following completion of the RCT, a subset (N=60) of RCT completers will be asked to participate in cognitive debriefing interviews. Participants will be asked to comment on specific aspects of the registry that were most beneficial in overcoming barriers and implementing EBP's in everyday clinical practice, and on those aspects that were least useful or clinically relevant. Impact on practice-related stress and burnout will also be discussed. GOAL: If successful, we plan to maintain and expand the PTSD Practitioner Registry as a novel mechanism for research and training of mental health practitioners across multiple practice settings.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

PTSD, trauma, Clinical Practice Guidelines (CPGs), best practices, qualitative interview, survey development

- 3. ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Goals up to October 2016 (all research sites contributed to completing all SOW tasks, which are listed below):

- 1) Obtain IRB approval from Stanford University; NERI; DoD; and VA Palo Alto Healthcare System (10/14-3/15) 100% complete on 06Jul2015: In order to streamline the study in the long-term, DoD requested an IRB deferral to Stanford IRB. This additional process shifted the timeline for Year 1 major tasks. Following this initial delay, all tasks have proceeded as anticipated and the project is on target to be completed as expected in Years 2-4.
- 2) Develop and pre-test interview modules (10/14-11/14) 100% complete on 03/15
- 3) Recruit providers for interview assessments (10/14-03/15) 100% complete as of 05Nov2015
- 4) Conduct provider interview assessments, n=60 (03/15-06/15) 100% complete on 05Nov2015. A total of 54 interviews were conducted. Please see rationale in the goals section.
- 5) Code, QC, and analyze interviews (03/15-06/15): 100% complete as of 27May2016
- 6) Prepare final descriptive report of needs assessment interviews (06/15-07/15): 100% complete as of 27May2016
- 7) Develop initial registry format (10/14-11/14) 100% completed Jun2015.
- 8) VHA web host programmers provide specifications and guidance to web programmers and database programmers (10/14-11/14) 100% completed on 5Feb2015
- 9) Develop on-line materials to assess the feasibility and usability of the registry (5/15-6/15) 100% completed on 25Aug2015
- 10) Completion of on-line questions and pre-testing of PTSD Provider Survey (7/15-8/15) 100% completed in 08/15
- 11) Develop provider recruitment materials (7/15-11/15) 100% complete on 26Oct2015
- 12) Define and provide nonmonetary incentives for regular use of the registry (7/15-11/15) 100% complete on 26Feb2016. The team has determined how we can provide clinicians with resources that will allow clinicians in all sectors to receive CEUs, in addition to integrating badging, interactive resources, and feedback mechanisms into the site, all of which we believe will be incentives for return site use.
- 13) Program automatic e-mail reminders/interaction with providers (7/15-11/15) Content 100% complete on 28Mar2016. Email reminders have been finalized and will be sent out by VA study staff.
- 14) Finalize all provider content (9/15 – 11/15) 100% complete on 26Feb2016
- 15) Finalize all modifications to registry design (11/15): 100% complete on 25Apr2016. The registry website went live on 25Apr2016.

- 16) Program and test randomization system for RCT (3/16): 100% completed on 28Mar2016
- 17) Program Active Registry surveys (PTSD Provider Survey) and materials (9/15-11/15): 100% completed on 30Mar2016
- 18) Program Baseline Assessment Measures (9/15 – 11/15): 100% completed on 28Mar2016
- 19) Develop message for Email Only Controls (9/15 – 11/15): 100% completed on 21Mar2016
- 20) Develop provider recruitment materials (7/15 – 11/15) 100% complete on 17Feb2016
Protocol, ICFs and recruitment materials were developed by the study team for Phase II.
- 21) Recruit, screen and collect data on N = 600 providers in the RCT (11/15 – 11/17):
Recruitment started 05Apr2016, 83% complete as of 03Oct2016
- 22) Monitor participation rates; data collection and data quality (11/15 – 11/17): Task started on 05Apr2016

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

IRB Approval:

- Stanford received IRB approval for v.2.1 of the protocol and Phase II regulatory documents (19Feb2016)
- NERI received IRB approval for v.2.1 of the protocol and Phase II regulatory documents (24Feb2016)
- WRAIR received commander approval for v.2.1 of the protocol and Phase II regulatory documents (21Mar2016)
- HRPO approval was provided for Stanford, NERI and WRAIR (25Feb2016, 04Mar2016, 04Mar2016)
- Stanford received IRB approval for v. 2.2 of the protocol and recruitment flyer (26Jul2016)
- NERI received IRB approval for v. 2.2 of the protocol and recruitment flyer (29Jul2016)
- WRAIR received commander approval for v. 2.2 of the protocol and recruitment flyer (15Aug2016)

Qualitative Assessment:

- Qualitative Interviews were scheduled to begin this quarter but were delayed due to delays with obtaining the DoD deferral to Stanford IRB and then full HRPO IRB approval. Recruitment for qualitative interviews began on 07Jul2015.
- Qualitative interviews continue. A total of 54 interviews were completed as of November 2015. A total of 60 interviews were anticipated to be completed for Phase I; however, the DoD was informed by the Navy and Air Force that neither branch would be able to provide lists for this phase of the project; Both branches confirmed support for the second phase of the project and will be able to provide lists for Phase II. Because the qualitative interviews to date have achieved information “saturation”, which is the intention of qualitative interviews, it was decided that no further qualitative interviews will be necessary beyond the current targeted n=54.

Survey development:

- Final survey content completed (15Dec2015)

Web development:

- Website go-live (25Apr2016)

Survey programming:

- Survey programmed into eCOS (28Mar2016)

Recruitment

- Initial recruitment email sent (05Apr2016)
- Recruitment continues for RCT (83% complete as of 03Oct2016)
-

Additional Tasks:

- Recruitment Plan was finalized for Phase II
- Presentation at 2016 MHSRS (August 2016)

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. “Training” activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. “Professional development” activities result in increased knowledge or skill in one’s area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

The study team developed a poster that was presented at the 2016 MHSRS conference.

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

The Advisory Board members are key members within the PTSD community from the three service sectors (VHA, DoD, and community). One of the key functions of the advisory board will be to assist with dissemination of key findings once the study has concluded. An email update to the advisory board was provided in April 2016. A follow-up meeting will occur in October 2016.

What do you plan to do during the next reporting period to accomplish the goals?

If this is the final report, state “Nothing to Report.”

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

During the next reporting period we plan to accomplish the following:

- Complete recruitment (n=600) for RCT
- Begin the 6 month assessment for those participants that completed baseline
- Develop discussion guide for Phase II interviews

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to report.

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to report.

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report.

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to report.

- 5. CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Due to the limited support for recruitment from the Airforce and Navy, recruitment for the DoD sector has been slower than anticipated, despite significant efforts on behalf of the team. To compensate for this, we have: 1) increased recruitment efforts in the DoD sector, including personal presentations to DoD mental health clinicians by Dr. Wilk and renewed efforts at support from Behavioral Health Chiefs in these sectors; 2) increased our recruitment quotas in the VA and Community to compensate for slower recruitment in DoD. Via these means, we anticipate reaching our overall recruitment goal for the study of 600 mental health clinicians from three major service sectors.

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

There have been no changes that had a significant impact on expenditures.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

There have been no significant changes in use or care of human subjects.

Significant changes in use or care of vertebrate animals.

n/a

Significant changes in use of biohazards and/or select agents

n/a

- 6. PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”

- **Publications, conference papers, and presentations**

Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume; year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

1. Wilkinson, A., Ortigo, K., Simon, E., Coleman, J.L., Clarke-Walper, K., Zincavage, R., Marceau, L., Wilk, J., Ruzek, J.I., Rosen, R.C. The PTSD Practitioner Registry: A Novel Tool for Dissemination and Training of Best Practices/Clinical Practice Guidelines for PTSD Providers. Poster presented at the Military Health System Research Symposium, Fort Lauderdale, FL, USA, Aug 15-17, 2016.

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report.

Other publications, conference papers, and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to report.

- **Website(s) or other Internet site(s)**

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to report.

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

Nothing to report.

- **Inventions, patent applications, and/or licenses**

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report.

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *biospecimen collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate “no change.”

Example:

<i>Name:</i>	<i>Mary Smith</i>
<i>Project Role:</i>	<i>Graduate Student</i>
<i>Researcher Identifier (e.g. ORCID ID):</i>	<i>1234567</i>
<i>Nearest person month worked:</i>	<i>5</i>

<i>Contribution to Project:</i>	<i>Ms. Smith has performed work in the area of combined error-control and constrained coding.</i>
<i>Funding Support:</i>	<i>The Ford Foundation (Complete only if the funding support is provided from other than this award).</i>

Name: Josef Ruzek

Project Role: Principal Investigator

Nearest person month worked: 4

No change.

Name: Robyn Walser

Project Role: Co-Investigator

Nearest person month worked: 1

No change.

Name: Sara Landes

Project Role: Co-Investigator

Nearest person month worked: 1

No change.

Name: Benjamin Graham

Project Role: Co-Investigator

Nearest person month worked: 1

No change.

Name: Erica Simon

Project Role: Project Manager

Nearest person month worked: 12

No change.

Name: Kile Ortigo

Project Role: PTSD Resource Specialist

Nearest person month worked: 12

No change.

Name: Samantha Regala

Project Role: Administrative Research Assistant

Nearest person month worked: 9

No change

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to report.

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:

Organization Name:

Location of Organization: (if foreign location list country)

Partner’s contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner’s facilities for project activities);*
- *Collaboration (e.g., partner’s staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner’s staff use each other’s facilities, work at each other’s site); and*
- *Other.*

Organization Name: New England Research Institutes

Location of Organization: Watertown, MA

Partner’s contribution to the project: The NERI team is the co-awardee of the project. NERI and NCPTSD work collaboratively on all portions of the project.

Organization Name: Walter Reed Army Institute of Research (WRAIR)

Location of Organization: Silver Spring, MD

Partner’s contribution to the project: The WRAIR team is also a part of the overall team and is involved in the scientific and programmatic functions of the project.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.

9. **APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.